

Appl. No. : 10/821,626  
Filed : April 9, 2004

## REMARKS

The Applicants have amended the Specification. The specific changes to the Specification are shown above in the Amendments to the Specification, wherein the insertions are underlined and the ~~deletions are stricken through~~. The Applicants have amended Claims 5 and 6, and cancelled Claims 1-4 and 16-29. Thus, Claims 5-15 and 59 are presented for examination. The specific changes to the amended claims are shown above in the Amendments to the Claims, wherein the insertions are underlined and the ~~deletions are stricken through~~. The Applicants respond below to rejections made by the Examiner in the Office Action of July 28, 2006.

### **I. Objections to the Disclosure**

The Examiner has objected to paragraph [0048] of the disclosure for reference to Figures 1 and 2, because there are no figures in the present application. Applicants have amended the specification to remove the reference. Applicants respectfully submit that the amendment overcomes the objection.

### **II. Rejections under 35 U.S.C. § 112**

The Examiner has rejected Claim 5 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states that Claim 5 is confusing because it is dependent upon Claim 1, which was not elected for prosecution. Applicants have amended Claim 5 so that it is now an independent claim. Applicants respectfully submit that the amendment over comes the rejection.

The Examiner has rejected Claims 5-15 and 59 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that “[t]he specification discusses making antibodies in general and discloses a method of making the compound shown in claim 1,” but argues that “[t]here is no disclosure that the antigen made has ever been used to make antibodies and especially not catalytic antibodies.”

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath*

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*Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). However, an Applicant need not precisely recite each and every element of a claim limitation in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).

Applicants respectfully submit that the present specification discloses not only the haptens of Structure 1 and Structure 2, but also the coupling of such haptens to any of a variety of carrier molecules to make an immunogenic conjugate. *See ¶¶ [0044]-[0045]*. The present specification also teaches raising, screening, and isolating antibodies by using the immunogenic conjugate. *See ¶¶ [0046]-[0048]*. Because following these techniques leads to a reasonable expectation of success in making the claimed antibodies, one of ordinary skill would understand that the inventors were in possession of the claimed invention.

The Examiner has also rejected Claims 5-15 and 59 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner also refers to the unpredictability of the art of making catalytic antibodies, and cites various references discussing catalytic antibodies, indicating that which some experimentation was required to identify useful catalytic antibodies, and indicating that catalytic antibody activity is generally "very modest" when compared with enzymes.

Enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). "To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *See In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

As discussed above, the present specification teaches haptens, making immunoconjugates from those haptens, and raising, screening, and isolating antibodies. The act of screening antibodies for activity is understood in the art, as indicated by the references cited by the Examiner. A need to screen antibodies to determine whether they are catalytic antibodies is not undue experimentation, and thus should not negative patentability. Applicants thus respectfully submit that by following the teachings of the present specification, one of ordinary skill in the art

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would thus have a reasonable expectation of success to prepare antibodies according to the present invention.

The Applicants respectfully request withdrawal of the § 112 rejections.

**CONCLUSION**

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art.


In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested. If the Examiner has any questions which may be answered by telephone, the Examiner is invited to call the undersigned directly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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